REMARKS

Status of the Claims

Claims 2, 3, 6-9, 11-14, 19, 22-27, 30-38, 41, 42, 46-54, 59, 60, 63-67, 69-70 and 72-118 are pending in the present application. Claims 1, 4, 5, 10, 15-18, 20, 21, 28, 29, 39, 40, 43-45, 55-58, 61, 62, 68 and 71 have been cancelled without prejudice or disclaimer of the subject matter contained therein.

The listing of withdrawn claims should be clarified in view of the amendments made to the claims in the prior response. The non-elected groups in the requirement for restriction are basically limited to the various withdrawn uses. For instance, there is no technical or legal basis for withdrawing composition claims 3, 8, 9, 13 and 60 which depend on the elected invention.

Claim Rejections - 35 USC §112

Claims 7, 12, 14, 22, 23, 42, 50, 51, 59, 66, 72, 92, 93, 95 and 112-114 are rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth on pages 4-6 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner alleges that the recitations "high and low molecular weight ranges" and "low purity" are indefinite because they are unclear relative terms and because "high" and "low" have an entirely subjective meaning. Applicants do not agree

with the Examiner for the reasons of record. However, in order to expedite allowance of the present claims, or alternatively in order to reduce issues on appeal, Applicants have deleted the offending phrases.

With respect to the phrase "high and low molecular weight ranges," Applicants have substituted various molecular weight ranges for this phrase.

With respect to the phrase "low purity," Applicants have basically substituted substantially all of the relevant portion of claim 72 for this offending phrase. The Examiner provides no basis for the rejection of claim 72. Thus, there is no prima facie case of indefiniteness set forth with respect to claim 72.

With respect to claim 22, Applicants have deleted the irrelevant proviso.

With respect to claim 112, Applicants have clarified that the effective amount is a nutritionally effective amount. Further, there is no explanation as to why claim 113 is similarly rejected.

The Examiner's comments that the definitions in the specification for the various terms are not clear is not correct. Applicants merely have provided a cascading set of preferred amounts of ingredients. However, this issue is moot in view of the amendments to the claims.

Each of the rejections under 35 U.S.C. 112, second

paragraph, has been discussed above. Based on the above-mentioned amendments and remarks, the rejections under 35 U.S.C. 112, second paragraph, should be withdrawn by the Examiner.

Claim Rejections - 35 U.S.C. §102

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 73-76, 78, 80, 81, 91-95, 112, 117 and 118 are rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,303,676 to Balazs for the reasons set forth on pages 6-9 of the Office Action. Claims 71, 72, 77, 79, 82-90 and 113-115 are free of this rejection.

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 73-76, 78, 80, 81, 91-95, 112, 117 and 118 are rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by WO 97/25051 to Turley for the reasons set forth on pages 9-10 of the Office Action. Claims 71, 72, 77, 79, 82-90 and 113-115 are free of this rejection.

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 73, 84, 90, 92-95, 112, 117 and 118 are rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by WO 92/22585 to Gallina for the reasons set forth on pages 10-11 of the Office Action. Claims 71, 72, 74-83, 91 and 113-115 are free of this rejection.

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 73, 76, 77, 82-84, 92-95, 112, 117 and 118 are rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by JP 9-262057 for the reasons set forth on page 7 of the Office Action. Claims 71, 72, 74, 75, 78-81, 85-91 and 113-115 are free of this rejection.

These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

Rejection Over Claim 19

Claim 19 relates to a composition which comprises at least one orally ingestable or mucosally absorbable complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides, and glycosaminoglycans, wherein said complex carbohydrates are present in an amount of 0.0001 mg to 100 mg, and wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or mucosally to mammals, with the proviso that said composition does not contain an essential oil as an active ingredient, and a carrier selected from the group consisting of a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an

ingestable foam, an ingestable capsule, a tablet, an ingestable tablet, an ingestable dissolvable tablet, a suppository, and an ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

The Examiner should note that the subject matter of claim 71 has been incorporated into claim 19. Claim 19 is amended to overcome the rejections under 35 U.S.C. 112. Thus, the rejections of claim 19 and all claims dependent thereon under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Rejection Over Claim 22

Claim 22 relates to a composition which comprises, as an active ingredient, a pharmacologically effective amount of at least one orally ingestable or mucosally absorbable complex carbohydrate selected from the group consisting of a mixture of molecular weight ranges of hyaluronic acid, wherein said molecular weight ranges comprise at least one fraction from 1,000 to less than 50,000 daltons, from 100,000 to 300,000 daltons or greater than 750,000 daltons, and wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or mucosally to mammals, and a carrier selected from the group

consisting of a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable capsule, a tablet, an ingestable tablet, an ingestable dissolvable tablet, a suppository, and an ingestable nutritional supplement.

The Examiner should note that substantial portions of the subject matter of claim 72 have been incorporated into claim 22. Claim 22 is amended to overcome the rejections under 35 U.S.C. 112. Thus, the rejections of claim 22 and all claims dependent thereon under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Rejection Over Claim 23

Claim 23 relates to a composition which comprises as an active ingredient a pharmacologically effective amount of at least one orally ingestable or mucosally absorbable complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycans, wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or mucosally to mammals, and a carrier selected from the group consisting of a drink, a drink

mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable capsule, a tablet, an ingestable tablet, an ingestable dissolvable tablet, a suppository, and an ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

The Examiner should note that substantial portions of the subject matter of claim 72 have been incorporated into claim 23. Claim 23 is amended to overcome the rejections under 35 U.S.C. 112. Thus, the rejections of claim 23 and all claims dependent thereon under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Rejection Over Claim 70

Claim 70 relates to an orally ingested or mucosally absorbed pharmaceutical composition selected from the group consisting of a drink, a drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, which comprises as an active ingredient a pharmacologically effective amount of at least one complex carbohydrate selected from the group consisting of

oligosaccharides, sialylated oligosaccharides, polysaccharides, and glycosaminoglycans, wherein said at least one complex carbohydrate comprise at least one fraction having a molecular weight range from 1,000 to less than 50,000 daltons, from 100,000 to 300,000 daltons or greater than 750,000 daltons, wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or mucosally to mammals, with the proviso that said composition does not contain an essential oil as an active ingredient, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

The Examiner should note that substantial portions of the subject matter of claim 72 have been incorporated into claim 70. Claim 70 is amended to overcome the rejections under 35 U.S.C. 112. Thus, the rejections of claim 70 and all claims dependent thereon under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Rejection Over Claim 73

Claim 73 relates to an orally ingested or mucosally-absorbed pharmaceutical composition selected from the group consisting of drink, drink mix, food, candy, mouthwash,

toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, which comprises an effective amount of at least one complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides, and glycosaminoglycans for treating inflammation, wherein said at least one complex carbohydrate has at least one fraction having a molecular weight range from 1,000 to less than 50,000 daltons, from 100,000 to 300,000 daltons or greater than 750,000 daltons, and wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or mucosally to mammals, with the proviso that said composition does not contain an essential oil as an active ingredient, wherein said orally ingested or mucosally-absorbed pharmaceutical composition is selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

The Examiner should note that substantial portions of the subject matter of claim 72 have been incorporated into claim 73. Claim 73 is amended to overcome the rejections under 35 U.S.C. 112. Thus, the rejections of claim 73 and all claims dependent thereon under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Rejection Over Claim 92

Claim 92 relates to an orally ingested or mucosally absorbed pharmaceutical composition selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, which comprises, as an active ingredient, a pharmacologically effective amount of at least one complex carbohydrate selected from the group consisting of a mixture of molecular weight ranges of hyaluronic acid, wherein said molecular weight ranges comprise at least one fraction from 1,000 to less than 50,000 daltons, from 100,000 to 300,000 daltons or greater than 750,000 daltons, and wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or

mucosally to mammals, with the proviso that said composition does not contain an essential oil as an active ingredient, wherein said orally or mucosally-administered pharmaceutical composition is selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

The Examiner should note that substantial portions of the subject matter of claim 72 have been incorporated into claim 92. Claim 92 is amended to overcome the rejections under 35 U.S.C. 112. Thus, the rejections of claim 92 and all claims dependent thereon under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Rejection Over Claim 94

Claim 94 relates to an orally ingested or mucosally-absorbed pharmaceutical composition selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet,

ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, which comprises as an active ingredient a pharmacologically effective amount of at least one complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycans, wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or mucosally to mammals, with the proviso that said composition does not contain an essential oil as an active ingredient, wherein said orally ingested or mucosally-absorbed pharmaceutical composition is selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

The Examiner should note that substantial portions of the subject matter of claim 72 have been incorporated into claim 94. Claim 94 is amended to overcome the rejections under 35 U.S.C. 112. Thus, the rejections of claim 92 and all claims dependent thereon under 35 U.S.C. 102(b) should be withdrawn by the

Examiner.

Rejection Over Claim 117

Claim 117 relates to a composition comprising at least one orally digestable or mucosally absorbable complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides, and glycosaminoglycans, wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or mucosally to mammals, and wherein said at least one complex carbohydrate is mixed in a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable capsule, an ingestable tablet, a chewable tablet, a dissolvable tablet, and an ingestable nutritional supplement so that they contain at least 0.00005 mg of the complex carbohydrate, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

The Examiner should note that substantial portions of the subject matter of claim 72 have been incorporated into claim 117. Claim 117 is amended to overcome the rejections under 35 U.S.C. 112. Thus, the rejections of claim 117 and all claims

dependent thereon under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Summary of Rejections Under 35 U.S.C. 102(b)

Claims 71 and 72 are free of the rejections under 35 U.S.C. 102. Substantially all of the subject matter of claim 71 has been incorporated into claim 19. Substantially all of the subject matter of claim 72 has been incorporated into the remaining independent claims that are rejected under 35 U.S.C. 102. Accordingly, the various rejections under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Rejection of Claims Over WO 97/25051 to Turley et al. Under 35 U.S.C. 103

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69-95, 112-115, 117 and 118 are rejected by the Examiner under 35 U.S.C. 103 over WO 97/25051 to Turley et al. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Turley et al. contemplates a new mode of administration (e.g. oral) for intravenous/injection grade HA. Previously, HA was administered intravenously or via injection using highly purified HA. Turley et al. found that the oral administration

of such pure HA was effective for treating restenosis. See page 3, lines 6-25 of the Turley et al. publication.

An example of the purity of the HA contemplated to be used by Turley et al. is described in the last two lines on page 11 of the cited reference. The description teaches that the Turely et al. composition passes the rabbit ocular toxicity test. In contrast, the present claims, as amended, recite "wherein said complex carbohydrate will cause reactions when injected into monkey eyes or joints of horses but will not cause reactions when applied to the skin of mammals or when delivered orally or mucosally to mammals." Clearly, a composition that causes reaction in monkey eyes will cause a reaction in the Turley et al. rabbit ocular toxicity test. Thus, the composition of Turley et al. does not suggest the claimed composition.

An additional indication that the Turley et al. preparations require high purity HA is that the preparations are to be "substantially pyrogen-free" (see page 10, line 14) and tested for endotoxin (page 8, lines 40-41; page 9, lines 22-23). The present invention does not require such purity and, in fact, the composition of the present invention allows for the presence of endotoxins (see page 3, lines 31-34 and page 4, line 1).

Turley et al. further indicate that "The formulation can be administered among other methods, intravenously, intra-articularly, intraperitoneally, intrapleurally..... or by direct

injection…." (see page 13, lines 28-30) The compositions of the present invention could not be safely administered by the above-mentioned routes as they are not pure enough.

The Examiner should also note that the Turley et al. publication is narrowly directed, from an enablement point of view, to the oral administration of hyaluronic acid for the prevention of restenosis before, during and/or after balloon angioplasty. For instance, note Figures 6-7.

Further, the description as a whole, at best, teaches that a suitable regimen for sustained maintenance of therapeutic levels of HA is the oral dosage amount(s) of 3-10 mg/kg of high grade HA in a sterile solution in order to inhibit restenosis. Turley et al. consistently emphasizes the need for sterile materials. See, for instance, page 6, lines 19-30, which teach suitable HA is that for intravenous use; page 7, lines 1 and 24, teach pharmaceutical grade HA; page 9, line 22, teach sterilized topical grade HA; page 10, line 1, and page 11, lines 10-13 teach the use of purified HA. Further, all testing is with high grade HA.

Accordingly, the Examiner should note that the Turley et al. composition is clearly limited to pharmaceutical grade hyaluronic acid as is discussed on pages 6-12 and on page 13, line 20 (e.g. use of injectable formulation). Moreover, all of

the Turley et al. claims are limited to pharmaceutical grade materials.

Turley et al. also clearly state that a molecular weight >600,000 daltons will not be orally effective (see page 12, lines 9-14). In fact, Turley et al. teach away from using any composition with a molecular weight >600,000 daltons. In the present invention, one of the molecular weight fractions recited by the amended claims is >750,000 daltons [e.g. claim 12, 22, 70, 73, 92] or >1,000,000 daltons [e.g. claim 38].

The Examiner concedes that Turley et al. fails to disclose "the use of all of the claimed oral administration forms, including tablets, capsules and food supplements, including animal treats, as the physical form of the orally administrable hyaluronic acid compositions disclosed therein." The Examiner alleges that it is obvious to use all of the claimed vehicles. However, the Examiner is unable to refer to a single portion of the reference that provides sufficient motivation to obtain the present invention. Clearly, the Examiner's position is a hindsight reconstruction of the prior art in view of Applicants' own disclosure.

Accordingly, the Examiner has not established a prima facie case of obviousness with respect to all of the claimed administration forms and instead relies on his personal opinion.

In the absence of a reference, the various claimed administration forms should also be in condition for allowance.

The Examiner has also failed to comment on the nutritional composition recited in claim 112 or why such a composition would be obvious.

Finally, Turley et al. does not utilize HA of the claimed purity. Thus, the present invention is not obvious over the teachings thereof.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee of $225.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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